K111566

OCT - 6 2011

Section B
1.

510(k) Summary

June 3, 2011

CARESTREAM Health, Inc.
150 Verona Street
Rochester, NY 14608

Contact: Christine Ehmann

Phone: 585-627-6473
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Device

Trade name:	DRYVIEW CHROMA Imaging System
Common name:	Inkjet Printer
Classification name:	Medical Image Hardcopy Device (21 CFR 892.2040)

Predicate device Codonics Horizon Ci Medical Image Multimedia Imager (K021054)

Description and Intended Use of Device

The DRYVIEW CHROMA Imaging System is intended to provide hard copy images from digital imaging source output signals. The device is intended for use with DRYVIEW CHROMA film and reflective media. The device will interface with a variety of digital modalities, including, but not limited to, CR (Computed Radiology), DR (Digital Radiology), CT (Computerized Tomography), MRI (Magnetic Resonance Imaging). The images are to be used for medical diagnosis and referral to physicians and their patients. The DRYVIEW CHROMA Imaging System is not intended for use with FFDM or CR Mammography systems.

Technological Characteristics

The DRYVIEW CHROMA Imaging System is an inkjet printing system. The DRYVIEW CHROMA Imaging System (CHROMA System) receives medical data including image and clinical report data from a digital modality. This data is received from medical image source devices (modalities) over a network and communicated to the CHROMA device via digital communication standard, DICOM. User control is performed directly by the modality or through the host control.

The CHROMA System device prints the information received using piezoelectric inkjet technology. Tiny ink droplets are propelled from pizeoelectric nozzles in the printhead onto the media to form the image or report communicated by the digital modality.

The CHROMA System device prints on transparent polyester based (film) as well as reflective (paper) media. Media is removed from a cartridge and transported into the CHROMA System device. Print data and media merge within the device.

The CHROMA System employs the use of test patterns to verify imaging performance. A test pattern generator is incorporated to assure consistency between input signals and output density.

Software is used to control the image management and machine functions. The information sent to the DICOM interface is used by the DICOM Interface to choose the correct set of printing parameters and halftone patterns for optimal image quality.

Performance Data
Safety and effectiveness are assured via meeting voluntary standards, including: DICOM, IEC 62304, UL 60950, IEC 60601-1-2 and ISO 14971.

Conclusion
The CHROMA System, like the predicate, has no patient contact. The CHROMA System device does not control, monitor or otherwise affect any devices directly connected to or affecting the patient. Medical personnel review images and hardcopy reports printed by the subject device and its predicate. The images or reports may be reprinted, if desired, by the end user since the original image data or report is stored on a connected modality..

As with the predicate device, a test pattern generator is incorporated to assure consistency between input signals and output density. Both are hardcopy printers that employ the use of test patterns to verify imaging performance.

The DRYVIEW CHROMA Imaging System and predicate device Codonics Horizon Ci Medical Image Multimedia Imager (Codonics Horizon Ci) have both been designed to the equivalent or comparable safety standards. The hazards associated with the DRYVIEW CHROMA Imaging System do not pose any new safety or efficacy issues compared to those associated with the predicate device as well as other medical image hardcopy devices.

Carestream Health concludes that the DRYVIEW CHROMA Imaging System is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Christine Ehmann
Regulatory Affairs Director
CARESTREAM Health, Inc.
150 Verona Street
ROCHESTER NY 14608

OCT - 6 2011

Re: K111566
Trade/Device Name: DRYVIEW CHROMA Imaging System
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: August 10, 2011
Received: August 12, 2011

Dear Ms. Ehmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111566

Device Name: DRYVIEW CHROMA Imaging System

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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